

**Rompe JD, Decking J, et al. Repetitive Low-Energy Shock Wave Treatment [ESWT] for Chronic Lateral Epicondylitis in Tennis Players. Am J Sports Med 2004;32(3):734-743.**

Design: Randomized clinical trial

Population/sample size/setting:

- 78 tennis players (38 women, 40 men, mean age 45) treated for lateral epicondylitis in a university orthopedics department in Mainz, Germany
- Eligibility criteria were playing recreational tennis for at least 1 hour per week prior to onset of symptoms, having lateral elbow pain for at least 1 year, having a positive MRI (increased signal intensity of the extensors), having had a review of stroke technique and equipment review by a tennis professional, with failure of at least 3 conventional treatments (including at least 3 local injections, at least 10 sessions of PT, and at least 3 weeks of NSAID), with at least a 2 month interval since the last conservative treatment, and baseline of at least 4 points on a 0 to 10 VAS during resisted wrist extension (Thomsen test)
- Exclusion criteria were local arthritis, rheumatoid arthritis, cervical compression, previous surgery on the treated elbow, previous ESWT to any site, pregnancy, coagulation abnormalities, and any additional treatment between ESWT and 3 month follow-up except for elbow braces

Main outcome measures:

- Randomized to 3 weekly sessions of either active ESWT (n=38) or sham ESWT (n=40)
- Active ESWT involved clinical focusing of the shock head (placing it at the site of maximal reproduction of discomfort), with administration of 2000 shocks of  $0.09 \text{ mJ/mm}^2$  at a frequency of 4 Hz, with each session lasting up to 30 minutes
- Sham ESWT used an identical-appearing setup, with the typical sound created by the lithotripter, with a polyethylene foil completely reflecting the shock waves so that no energy was transmitted to the elbow
- Both active and sham ESWT patients were told to stop playing tennis until at least 1 week after the last treatment session
- Apart from an elbow brace, no other therapies (including PT and analgesics) were permitted until the 3 month follow-up
- At 3 months, the code was broken, and patients in the sham ESWT were offered the opportunity to have active ESWT, and 24 of them accepted
- Primary outcome was reduction on Thomsen test score between baseline and 3 month follow-up; both groups had a mean score of 7.1 at baseline, but the mean 3 month score for active ESWT was 3.6 and for sham it was 5.1
- Other outcomes were measured at 3 months and at 12 months; one outcome was an upper extremity function scale, measuring difficulty with daily tasks (sleeping, writing, opening jars and doors, washing dishes, etc)

- This functional scale improved from 50.3 to 26.9 in the active ESWT group at 3 months, but from 49.1 to 38.2 in the sham ESWT group
- Maximal grip strength improved equally in both groups over time
- At 3 months, 65% of the active ESWT group and 35% of the sham ESWT group reported that they could perform activities at the desired level, including recreational tennis
- 36 of 38 patients in the active ESWT group and 21 of 40 patients in the sham ESWT group reported pain during the treatment session
- After the last treatment session, 18 of 40 sham ESWT patients thought they had received active ESWT; 29 of 38 active ESWT patients correctly guessed their treatment assignment

#### Authors' conclusions:

- These results differ from some previous trials of ESWT in showing a significant of active ESWT over placebo
- The current trial differed in 3 important ways from the “negative” study: (1) this trial did not give local anesthesia when ESWT was administered, (2) each patient received a standard number of shocks at the same energy intensity, (3) no treatment except for an elbow brace was allowed between the end of ESWT and the 3 month follow-up
- The study limitations include its being only of tennis players, having the majority of active ESWT patients correctly guessing their treatment assignment, and having broken the code at 3 months, so that long-term results need to be assessed in a separate trial
- Low-energy ESWT as applied in this trial confers a significant benefit compared to sham treatment 3 months after intervention
- Until shown otherwise, no pain medication is recommended during and up to 3 months after repetitive low-energy ESWT

#### Comments:

- Meticulous efforts were taken to protect results from bias, including having patients wait in separate waiting rooms to avoid meeting one another, keeping assessment blinded, good accounting of dropouts, and clear concealment of allocation
- The authors attribute the difference between their results and those of other studies to the standard dosing, not using local anesthesia, and the avoidance of other treatments after ESWT: however, the study population was athletically active and a positive MRI was required for entry into the study
- The role of the MRI as an inclusion criterion is not made clear; Figure 2 shows that only 6 of 93 patients were excluded for not meeting inclusion criteria, but it is not clear how many of these failed to meet MRI criteria
- Almost all of the patients in the active ESWT group reported pain with treatment, but continued treatment anyway, and accepted the protocol stipulation requiring them not to use analgesics for 3 months after completion of ESWT; this suggests that the study population had characteristics which pose a challenge to generalizing the results to other populations

- One such characteristic of this study population could be a high level of pain tolerance and an ability to function well in spite of elbow pain
- As the authors note, their study was done in one facility with one experienced operator, who periodically readjusted the shock head position every 200 to 400 shocks (every 50 to 100 seconds) to precisely treat the tender area; this may also be a factor accounting for some of the difference in results, and could not be done if local anesthesia had been administered

Assessment: High quality methodologically; threats to internal validity were taken into account by the authors and overcome. Only short-term (3 month) outcomes were clearly demonstrated. Application to different populations may require some deliberation. The null results reported by Haake et al in 2002 may be due to selection of a patient population which does not participate in tennis, and to administering ESWT using local anesthesia.